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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,464

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Masahiro Kawaguchi

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,464

Applicant(s)

KAWAGUCHI, MASAHIRO

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-3 and 12-16 in papers filed 27 February 2006 is acknowledged. The traversal is on the grounds that it would not be undue burden to examine the claims of all groups I and II. However, it is maintained that undue burden would be required to examine the claims of groups II along with claims of group I as evidenced by the fact that the claims of groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of invention II. For example a search of the subject matter of Invention I would encompass structural components of the system e.g. substrate of conductive material, heater, cooler, temperature controller while a search of the subject matter of Invention II would encompass method steps for gene detection e.g. sample-probe contact, and sample-specific detection. As such, the searches for Inventions I and II would not be co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-11 are withdrawn.

Claims 1-3 and 12-16 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 12, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 3 are indefinite in Claim 1, line 9 for the recitation “on the back of the substrate to the substrate surface” because the syntax is confusing, because “the back” and “the substrate surface” lack proper antecedent basis. It is suggested that the claim be amended to clarify.

Claims 1 and 3 are indefinite in Claim 1, line 11 for the recitation “and in contact with the back of the substrate” because it is unclear what the recitation modifies i.e. are the fragments in contact with the back of the substrate.

Claims 1 and 3 are indefinite in Claim 1, line 14 for the recitation “the amount of heat flowing” because the recitation lacks proper antecedent basis in the claim.

Claims 1 and 3 are indefinite in Claim 1, lines 18-20 for the recitation “the temperature of the substrate disposed in contact being controlled through the temperature control of the heat-conductive material”. The recitation is confusing because it is unclear what structure is being described. The phrase “in contact” appears to be the only structural relationship, but the recitation does not describe to what the substrate is “in contact”. It is suggested that the claim be amended to clarify.

Claims 2 and 16 are indefinite in Claim 2, line 9 for the recitation “on the back of the substrate to the substrate surface” because the syntax is confusing. It is suggested that the claim be amended to clarify.

Claims 2 and 16 are indefinite in Claim 2, line 15 for the recitation “the amount of heat flowing” because the recitation lacks proper antecedent basis in the claim.

Claims 2 and 16 are indefinite in Claim 2, lines 19-22 for the recitation “the space and the substrate surface, which are in contact with the heat-conductive material”. The recitation is confusing because lines 15-19 define the surface as having the heat-conductive material. Therefore the “in contact with” recited in lines 19-22 appears to contradict the meaning of lines 15-19. It is suggested the claim be amended to clarify.

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Claim 3 is indefinite for the recitation “a composite of these two or more” because one of ordinary skill in the art would not be appraised of the meets and bounds of “or more”.

Claim 12 is indefinite in lines 7-8 for the recitations “the side opposite to the surface of the probe” and “the detecting target substance” because the recitations lack proper antecedent basis in the claim.

Claim 12 is indefinite in line 19 for the recitation “and in contact with the back of the substrate” because it is unclear what the recitation modifies i.e. are the fragments in contact with the back of the substrate.

Claim 12 is indefinite in line 12 for the recitation “the amount of heat flowing” because the recitation lacks proper antecedent basis in the claim.

Claim 12 is indefinite in lines 16-18 for the recitation “the temperature of the substrate disposed in contact being controlled through the temperature control of the heat-conductive material”. The recitation is confusing because it is unclear what structure is being described. The phrase “in contact” appears to be the only structural relationship, but the recitation does not describe to what the substrate is “in contact”. It is suggested that the claim be amended to clarify.

Claim 14 is indefinite in line 7 for the recitation “on the surface of the substrate to the substrate surface” because the syntax is confusing. It is suggested that the claim be amended to clarify.

Claim 14 is indefinite in line 13 for the recitation “the amount of heat flowing” because the recitation lacks proper antecedent basis in the claim.

Claim 14 is indefinite in lines 17-19 for the recitation “the temperature of the substrate disposed in contact being controlled through the temperature control of the heat-conductive material”. The recitation is confusing because it is unclear what structure is being described. The phrase “in contact” appears to be the only structural relationship, but the recitation does

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not describe to what the substrate is “in contact”. It is suggested that the claim be amended to clarify.

Claim 15 is indefinite in line 4 for the recitation “which have been immobilized” because it is unclear whether the recitation modifies the target or the probes. It is suggested that the claim be amended to clarify.

Claim 15 is indefinite in line 4 for the recitation “the substrate surface” because the recitation lacks proper antecedent basis in the claim.

Claim 15 is indefinite in line 7 for the recitation “on the surface of the substrate to the substrate surface” because the syntax is confusing. It is suggested that the claim be amended to clarify.

Claim 16 is indefinite for the recitation “a composite of these two or more” because one of ordinary skill in the art would not be appraised of the meets and bounds of “or more”.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim interpretation

The claims are drawn to a system comprising a substrate having immobilized nucleic acids, heat-conducting material in contact with the substrate, a heater or cooler and a temperature controller. As cited above, the claims contain numerous phrases that are indefinite and/or confusing. The claims are give the broadest reasonable interpretation in view of the broad and indefinite claim language.

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5. Claims 1, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370 issued 25 July 2000).

Regarding Claim 1, Yasuda et al disclose a system for temperature control of a nucleic acid probe substrate, the system comprising a heat conducting member (#132) on the back of the substrate, the probes (e.g. #41-46) immobilized on the surface of the substrate (#221) a heater (#225) in contact with the conductive material, a controller for controlling heat across the conductive material and heater (#133) wherein the temperature of the substrate is controlled the control of the heat conductive layer (Column 10, line 56-Column 11, line 62 and Fig. 10-11).

Regarding Claim 12, Yasuda et al disclose a probe substrate temperature control system, the system comprising a heat conducting member (#132) on the back of the substrate, the probes (e.g. #41-46) immobilized on the surface of the substrate (#221) a heater (#225) in contact with the conductive material, a controller for controlling heat across the conductive material and heater (#133) wherein the temperature of the substrate is controlled the control of the heat conductive layer (Column 10, line 56-Column 11, line 62 and Fig. 10-11).

Regarding Claim 13, Yasuda et al disclose a probe substrate comprising a substrate (#221) a plurality of probes immobilized onto the substrate (e.g. #41-46) and a heat conductive material (#131-132) in contact with the back of the substrate (Column 10, line 56-Column 11, line 62 and Fig. 10-11).

6. Claims 1-3 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996).

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Regarding Claim 1, Wilding et al disclose a system for temperature control of a nucleic acid probe substrate, the system comprising a heat conducting member comprising a heat-conductive material on the back of the substrate (i.e. heat-conductive substrate, Column 15, lines 30-40), the substrate having nucleic acid probes (bead-immobilized probes (Column 9, lines 36-46) on the substrate within the reaction chamber (#22, Column 10, lines 45-50) a heater and/or cooler (#57, Column 16, lines 47-58) in contact with the conductive material (substrate/reaction chamber Column 5, lines 8-15, Column 8, lines 29-43) a controller for controlling heat across the conductive material and heater (Column 16, lines 47-49) wherein the temperature of the substrate is controlled by the control of the heat conductive layer (Column 16, line 48-Column 18, line 10).

Regarding Claim 2, Wilding et al disclose a system for temperature control of a nucleic acid probe substrate, the system comprising a heat conducting member (cover #12) comprising a heat-conductive material (Column 17, lines 9-15) on a the substrate, facing and in contact with the substrate leaving a space (channel #20) for sample introduction, the substrate having nucleic acid probes (bead-immobilized probes (Column 9, lines 36-46) on the substrate within the reaction chamber (#22, Column 10, lines 45-50) a heater and/or cooler in contact with the conductive material (Column 17, lines 5-24) a controller for controlling heat across the conductive material and heater wherein the temperature of the substrate is controlled by the control of the heat conductive layer (Column 16, line 48-Column 18, line 10).

Regarding Claim 3, Wilding et al disclose the system of Claim 1 wherein the heat-conductive material is metal or a composite (i.e. ferromagnetic beads (Column 23, lines 13-28).

Regarding Claim 12, Wilding et al disclose a probe substrate temperature control system comprising a heat conducting member comprising a heat-conductive material on the back of the substrate (i.e. heat-conductive substrate, Column 15, lines 30-40), the substrate having nucleic acid probes (bead-immobilized probes (Column 9, lines 36-46) on the substrate within the reaction chamber (#22, Column 10, lines 45-50) a heater and/or cooler (#57,

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Column 16, lines 47-58) in contact with the conductive material (substrate/reaction chamber Column 5, lines 8-15, Column 8, lines 29-43) a controller for controlling heat across the conductive material and heater (Column 16, lines 47-49) wherein the temperature of the substrate is controlled by the control of the heat conductive layer (Column 16, line 48-Column 18, line 10).

Regarding Claim 13, Wilding et al disclose a probe substrate comprising a substrate having nucleic acid probes (bead-immobilized probes (Column 9, lines 36-46) on the substrate within the reaction chamber (#22, Column 10, lines 45-50) and a heat-conductive material on the back of the substrate (i.e. heat-conductive substrate, Column 15, lines 30-40) for controlling the temperature (Column 8, lines 28-43).

Regarding Claim 14, Wilding et al disclose a probe substrate temperature control system comprising a heat conducting member (cover #12) comprising a heat-conductive material (Column 17, lines 9-15) on a the substrate, facing and in contact with the substrate leaving a space (channel #20) for sample introduction, the substrate having nucleic acid probes (bead-immobilized probes (Column 9, lines 36-46) on the substrate within the reaction chamber (#22, Column 10, lines 45-50) a heater and/or cooler in contact with the conductive material (Column 17, lines 5-24) a controller for controlling heat across the conductive material and heater wherein the temperature of the substrate is controlled by the control of the heat conductive layer (Column 16, line 48-Column 18, line 10).

Regarding Claim 15, Wilding et al disclose a probe substrate, comprising substrate a plurality of bead-immobilized probes (Column 9, lines 36-46) immobilized on the substrate within the reaction chamber (#22, Column 10, lines 45-50) and a heat-conductive material (cover #12, Column 17, lines 9-15) on a the substrate, facing and in contact with the substrate leaving a space (channel #20) for sample introduction, the substrate having a heater and/or cooler in contact with the conductive material (Column 17, lines 5-24) a controller for controlling heat across the conductive material and heater wherein the temperature of the

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substrate is controlled by the control of the heat conductive layer (Column 16, line 48-Column 18, line 10).

Regarding Claim 16, Wilding et al disclose the system of Claim 2 wherein the heat-conductive material is metal or a composite (i.e. ferromagnetic beads (Column 23, lines 13-28).

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 26, 2006